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Required documents shall preferably be submitted electronically, in the way that the numbering can directly be assigned to the relevant documents. For submission the Deutsche Akkreditierungsstelle GmbH (DAkKS) provides a **structured zip-folder** where the required documents should be stored electronically and resend to the case manager. In individual cases documents must be submitted in hard copy. The case manager will inform you accordingly.


All documents/evidences must be submitted¹ before the assessment in due time². By sending the documents the CAB ensures DAkKS the completeness of the submitted documents. If necessary, further documents may be required by the case manager or the assigned assessor.

Documents must be submitted in German or English language.

No.	Document
1.	<p>Complete documentation of the management system of the RM-producer granted/applied scope of accreditation (quality management manual, procedures, work instructions, SOPs or other specifications with regard to the applied/accredited reference materials)</p> <p>The following instructions / documents must be included:</p> <ul style="list-style-type: none"> • Contractual arrangements • Production planning and - control • Material processing, - handling and - storage • Data handling (integrity and evaluation) • Metrological traceability of the certified value and its measurement uncertainty (CRM) • Evaluation of homogeneity • Stability evaluation and - monitoring • Charakterization of the material • Assignment of property values and their uncertainty (CRM) • Storage and distribution of the RM
2.	List of all quality management documents (including version and/or date of validity)
3.	Most recent management review
4.	<p>Evidence of organisational structure, ownership and legal form of the RM-producer (trade register excerpt, list of shareholders, organisation chart(s))</p> <p><i>If the certification body is part of an organisation (within the legal entity or within a larger corporate structure) the ownership structure, the integration within the organisation and the relations to other organisational units must be submitted with appropriate information (e. g. with detailed organisational charts and lists of shareholders of all sub-organisations)</i></p> <p>Evidences about structure, ownership and legal structure of the integrated legal entities as well as information about further accreditations of these legal entities must be submitted.</p>

¹ To submit documents incomplete or late can be punished as an administrative offence according to § 12 AkkStellG (Accreditation Body Act)


² The assessment for initial accreditation of the RM-producer will be scheduled not before the required documents are submitted completely. In case of surveillance, extension of accreditation or reaccreditation documents shall be submitted at least 6 weeks before the scheduled assessment.

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No.	Document
5.	Risk analysis and liability estimation for the calculation of an appropriate level of insurance and evidence of a liability insurance or an equivalent solution (especially for financial loss). Information on scopes with a statutory insurance obligation.
6.	List of employees stating their qualification/professional training/responsibilities at all levels of the activity of the RM-producer
7.	Standard contract with clients including current terms and conditions und if applicable with existing liability limitation clauses.
8.	Regulations for the use of marks ³ – if applicable
9.	List of existing contractual regulations with external personnel (e. g. consultants), contractors (sub-contractors) and other cooperation partners as far as involved in the conformity assessment activities as well as samples of relevant contracts.
10.	Impartiality declaration of the top management
11.	Up to date analysis of risks regarding the impartiality including the analysis of related bodies and presentation of the mechanism for safeguarding impartiality
12.	Explanation on used IT-systems and their function and a description of interfaces between those IT-systems as well as to external databases/archive systems including the process of release of those systems.
13.	List of reference materials produced in the last three years <i>(Entry in the attached Excel file LI-EU_RM_A1_EN)</i>
14.	One reference material certificate (CRM) or product information sheet (RM) for each of the applicant/accredited areas
15.	<p>Documents relating to subcontracting⁴ (if applicable):</p> <ul style="list-style-type: none"> • Documented procedure on subcontracting, including criteria for the involvement of subcontractors for all tasks subcontracted in the production of RM • List of subcontractors including subcontracted tasks, if applicable, structured according to the fields RM are produced • Evidences of competences for the operations performed by subcontractors (e.g. copies of an accreditation certificate with annex, audit reports or similar evidences) • All contracts with subcontractors
16.	Spatial plan indicating the areas relevant for RM production
17.	<p>List of equipment used for producing RM (without measuring instruments) with in-house registration (including rented equipment, if applicable)</p> <p>Information necessary: Inventory number, location, usage, indication of the equipment/type of equipment/item, manufacturer</p>


³ Only relevant if the reference material producer issues its own marks for use by itself or its customers.

⁴ Where appropriate, according to the annex to the application

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No.	Document
18.	<p>Last annual report with information on/data of the RM-producer and the produced RM <i>(Exception: Initial accreditation)</i></p> <p><i>The template to be filled in is included in the zip-folder. Document will be submitted to DAkKS electronically (Excel-document).</i></p>
19.	<p>Filled Partial Assessment Report/Checklist DIN EN ISO 17034</p> <p><i>The template to be filled in is included in the zip-folder. Document will be submitted to DAkKS electronically (Word-document).</i></p>
20.	<p>Normative documents within the scope of accreditation</p> <p>Submission of a copy of all certificate-relevant technical standards or standards for the activities of the RM-producer within the scope of accreditation, as far as DAkKS does not determine a different regulation.</p> <p>All standards, documents equivalent to standards, in-house methods etc., which form the basis for the production of (certified) reference materials within the scope of accreditation and contain requirements for the performance of activities within the scope of accreditation shall be submitted⁵. <i>(The provision is permitted license-free according to § 45 Copyright Act (§45 Urheberrechtsgesetz (UrhG))</i></p> <p><i>These documents will be send separately from the other listed documents in a separate zip-folder. The identification of the normative documents is contained in the respective file name. If the normative documents within the scope of accreditation have already been submitted by the RM-producer, only the normative documents concerning changes of the scope shall be submitted.</i></p>

⁵ Publicly freely accessible documents that are the subject of the accreditation scope do not have to be submitted.

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Additional required documents in case of using a non-accredited internal testing laboratory, or of non-accredited testing, calibration or examination procedures used for characterization of the material and, if applicable, determination of the assigned values.

Nr.	Unterlagen
21.	List of applied testing-, calibration- and examination procedures in the framework of RM-production
22.	List of RM used for the procedures mentioned in No. 21
23.	Current list for participation in proficiency testing, like ring- and interlaboratory comparisons as well as EQAS ⁶ according to published DAkkS-rules <i>(No submission of certificates)</i>
24.	<p>Metrological traceability: List of equipment with in-house registration (including used rental equipment, used working standards as well as equipment/facilities which are not under permanent control of the CAB).</p> <p>Necessary information: Inventory-No., location, measurand (of which an evidence of the metrological traceability must be available), name of the equipment/type of equipment/object, producer, calibration-/functional checks interval, identification/name of the evidence(s) regarding metrological traceability, type of measurement traceability (regarding 71 SD 0 005_e).</p> <p><i>Optional specifications: Testing standard, serial number, responsible person for the equipment, and others</i></p>
25.	Spatial plan with information on testing -, calibration -, examination areas including information about the use of mobile facilities for the testing -, calibration - and examination activities
26.	<p>In cases of testing- and calibration procedures: Partial Assessment Report/Checklist DIN EN ISO/IEC 17025, <u>section 6 and section 7 filled</u> (documents will be submitted to DAkkS electronically (Word-document))</p> <p>In cases of medical test methods: Partial Assessment Report/Checklist DIN EN ISO 15189, <u>section 4.1 and section 5 filled</u> (documents will be submitted to DAkkS electronically (Word-document))</p>

⁶ External Quality Assessment Schemes